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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,831	03/26/2004	Thomas R. Kozel	031673-3000	7955

22204 7590 04/27/2007  
NIXON PEABODY, LLP  
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WASHINGTON, DC 20004-2128

EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/809,831	<b>Applicant(s)</b> KOZEL ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 2October2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15-19,21,33-37,39-49 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-19,21,33-37,39-49 and 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

1. Applicants' Response to Final Office Action, received 2 October 2006, is acknowledged. Claims 15, 16, 21, 33, 34, 39, 40, 45, 51, and 56 have been amended. Claims 20, 38, 50, and 61 have been canceled.

Applicants' Notice of Appeal, received 2 October 2006, is acknowledged.

2. The Finality of the last Office Action is hereby withdrawn.
3. Claims 15-19, 21, 33-37, 39-49, and 51-60 are pending and under consideration.

### **Rejections Moot/Withdrawn**

4. The rejection of claims 20, 38, 50, and 61 under 35 U.S.C. 112, first paragraph, scope of enablement for detection or staging of anthrax infection, is moot in light of the cancelation of the claims.
5. The rejection of claims 33-36 under 35 U.S.C. 112, first paragraph, scope of enablement for detection or staging of anthrax infection, is withdrawn in light of the claim amendments.
6. The rejection of claims 15-19, 21, 36, 37, 39-49, and 51-60 under 35 U.S.C. 112, first paragraph, scope of enablement for detection or staging of anthrax infection, is withdrawn in light of the claim amendments.

### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 15-19, 21, 33-37, 39-49, and 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method for detecting or staging anthrax infection by determining the level of soluble  $\gamma$ D-PGA in a biological sample.

There are two issues of indefiniteness in the claims.

The first issue is that the specification, paragraph 0121, states: " $\gamma$ D-PGA for immunization was obtained from *Bacillus licheniformis* which was grown under conditions that stimulated production of PGA with the D isomer. A mAB that was generated from mice immunized in this manner was reactive with *Bacillus anthracis*  $\gamma$ D-PGA as shown by (i) precipitation in double immunodiffusion, (ii) a distinct quellung reaction and binding of fluorescently labeled mAB to whole bacterial cells, (iii) detection of  $\gamma$ D-PGA in sera of infected mice (see Example 5), and (iv) protection against pulmonary anthrax infection (see Example 6)".

Paragraph 0122 states: "A difference between  $\gamma$ D-PGA isolated from *Bacillus licheniformis* and *Bacillus anthracis* was the appearance of the antigens in double immunodiffusion. *Bacillus licheniformis*  $\gamma$ D-PGA produced a single precipitin line with a shape that was consistent with having a high molecular weight. *Bacillus anthracis*  $\gamma$ D-PGA produced two precipitin lines; the shape of one line was consistent with the antigen having a low molecular weight and the other was consistent with a high molecular weight."

Thus, utilizing the claimed methods, which do not recite precipitin patterns, it is unclear how one distinguishes between infection with *Bacillus licheniformis* (see Quan et al, 2000;

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Hannah, Jr., et al, 1999; Santini et al, 1995) and infection with *Bacillus anthracis* by merely detecting  $\gamma$ D-PGA or the level of  $\gamma$ D-PGA.

The second issue is based upon the specificity of the detection reagent. The specification details the production and characteristics of monoclonal antibodies which detect  $\gamma$ D-PGA. However, this specificity is not part of the claims. In fact, the immunoassays of claims 16-18 do not require antibodies with this specificity, and claims 33-36, 39-49, and 51-60 recite using an antibody listed as "anti-PGA". Thus, it is unclear how one determines a level of  $\gamma$ D-PGA utilizing antibodies without a specificity for  $\gamma$ D-PGA.

### **Conclusion**

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.


The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

April 25, 2007